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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/688,551

10/17/2003

Indranil Nandi

G-33422P1/GPI

1169

1095

7590

04/30/2007

NOVARTIS

CORPORATE INTELLECTUAL PROPERTY

ONE HEALTH PLAZA 104/3

EAST HANOVER, NJ 07936-1080

EXAMINER

AZPURU, CARLOS A

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

04/30/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/688,551	Applicant(s) NANDI ET AL.	
	Examiner Carlos A. Azpuru	Art Unit 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-20 is/are pending in the application.
- 4a) Of the above claim(s) 14-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2, 4-9, 12 and 13 is/are rejected.
- 7) ☒ Claim(s) 10 and 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Receipt is acknowledged of the amendment filed 02/09/2007.

The rejections under 35 USC 102(b) over Itoh et al and 35 USC 103(a) over Itoh et al in view of Ullah et al are hereby withdrawn.

The following rejection is maintained in this action:

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4-8, 12-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 6, 10-12,

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16-17 of copending Application No. 10/768,562 (US'562). Although the conflicting claims are not identical, they are not patentably distinct from each other because US'562 claims an antibiotic composition comprising (1) a core comprising an antibiotic, (2) an inner coating comprising a cellulose polymer which is not an enteric coating polymer, and (3) an outer coating comprising at least one enteric coating polymer (see claim 1). The particle size is between about 100 microns to about 650 microns (see claim 1). The cellulose polymer of the inner core is specifically recited as hydroxymethylpropyl cellulose at claim 6, and the enteric polymer coating is specifically recites as poly(methacrylic acid ethyl acrylate) at claim 12. Therefore, those of ordinary skill would have expected similar enteric drug delivery, as well as similar therapeutic results from the use of the instant composition given the claims of copending US'562. The instant claims would have therefore been obvious at the time of invention given the claims of copending US'562.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Response to Arguments***

Applicant's arguments filed 02/09/2007 have been fully considered but they are not persuasive.

Applicants asked that the rejection be held in abeyance until allowance was indicated. It is noted also that applicant refers to a double patenting rejection, so this

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remark is made purely to emphasize that the rejection is not statutory, but instead the judicially created doctrine of obviousness-type double patenting which can be overcome by a terminal disclaimer, rather than amendment of the claims. The rejection is maintained in this action.

The following is a new rejection made in view of a supplemental search:

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4-7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 8 and 9 of copending Application No. 10/575,691 (US'691). Although the conflicting claims are not

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identical, they are not patentably distinct from each other because US'691 claims an antibiotic composition comprising coated micropellets and optionally one or more excipients wherein the coated micropellets comprise (i) a core comprising at least one antibiotic; an inner coating comprising at least one cellulose polymer which is not an enteric coating polymer; and (iii) an outer coating comprising at least one enteric coating polymer, wherein said coated micropellets have a mean particle size of about 100 um to about 650 um. Cellulose polymers which are not enteric in nature are listed at claim 4. Enteric coating polymers are listed at claims 8 and 9. Therefore, those of ordinary skill would have found it well within their skill to claim the instant composition with a reasonable expectation of taste masking results. As such, the instantly claimed composition would have been obvious to one of ordinary skill in the art at the time of invention given the claims of copending US'691.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

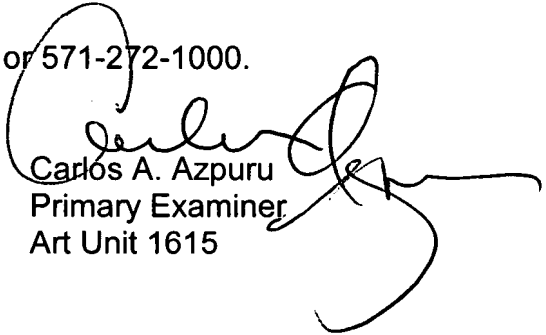
Claims 10-11 are objected to as dependent upon a rejected base claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Carlos A. Azpuru  
Primary Examiner  
Art Unit 1615

CA